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Date: May 22, 2008 Name: Mindy N. Rittner Reg. No. 57,803 Signature: _____

Attorney Docket No. 12730-11
Client Ref. No. PA-5327-CIP

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:)	
)	
Thomas A. Osborne et al.)	
)	Examiner: William H. Matthews
Serial No. 10/642,513)	
)	Group Art Unit No.: 3774
Filing Date: August 15, 2003)	
)	
For Stent and Method of Forming a)	
Stent with Integral Barbs)	

REPLY BRIEF

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

This Reply Brief is timely filed in response to the Examiner's Answer dated March 24, 2008.

ARGUMENTS

Reply to Examiner's Answer

The Examiner has failed to establish that U.S. 5,800,526 ("Anderson") discloses a stent with each and every feature recited in the rejected claims. These claims recite a stent with 1) an integrally formed barb (*i.e.*, the barb has not been attached to the wire during the manufacturing process); 2) that points in a predetermined direction at an angle relative to a longitudinal axis of the stent; and 3) that is unbent with respect to the wire and is free of weakening due to bending. The Examiner relies primarily on Anderson's drawings, none of which shows a stent with all of the recited features, and he ignores portions of the specification that directly contradict and undermine his position.

For example, the Examiner cites col. 6, lines 41-63 as evidence that Anderson's figures disclose integrally-formed barbs but fails to mention that lines 64-67, which immediately follow, teach non-integral barbs "formed independently of the stent and subsequently attached to it." Thus, none of Anderson's drawings, alone, necessarily depicts a stent with "integral barbs."

Next, the Examiner concludes that Figure 7 depicts "barbs 20 [that] are not bent with respect to the stent wire," because "bends 18 are shown to face outwardly such that barbs 20 also face outwardly." Thus, the Examiner admits that the stent structure undergoes bending during radial expansion, but suggests that the barbs, which are part of the stent structure, are unbent. The Examiner ignores the Anderson specification that explicitly teaches that the radial expansion of the stent occurs uniformly over the entire stent structure (*see* Anderson, col. 8, line 17) and that "the barbs will bend outwardly when the stent is expanded" (*see* Anderson, col. 8, line 17, col. 9, lines 15-26). Emphasis added.

The Examiner's reliance on Figure 7 of Anderson to show barbs that are allegedly unbent is misplaced as this figure is not an accurate depiction of an actual stent. Figure 7 is a side view of a portion of a cylindrical stent that has been expanded and flattened to be devoid of cylindrical curvature. Since this figure does not show the

cylindrical curvature of the stent structure, it cannot provide a complete view of the bending and distortion that Anderson explicitly discloses occurs upon radial expansion. To the extent Figure 7 does not depict the inherent curvature of the stent, it is impossible to discern at least part, if not all, of the bending experienced by the barbs during the radial expansion from this figure.

On the other hand, Figure 6 of Anderson illustrates a different view of the flattened stent of Figure 7 and clearly shows that the angle formed between the barb and the stent wire decreases as the entire stent structure undergoes the uniform radial expansion and plastic deformation explicitly taught by Anderson. Compare Anderson, Figures 4 and 6. The Appellant maintains that the Examiner has provided neither objective evidence nor cogent technical reasoning to support the assertion that unbent barbs, which are free of weakening due to bending, are *necessarily* present in Anderson's expanded stent.

"To establish inherency, the extrinsic evidence 'must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by person of ordinary skill. Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient."

In re Robertson, 169 F.3d 743, 745 (Fed. Cir. 1999). Emphasis added.

Finally, the Examiner suggests that the "predetermined direction" feature is met by Anderson's disclosure of a barb that points in an outward direction, as opposed to an inward, distal, or proximal direction. This argument entirely misses the point of the feature and fails to provide any patentable weight to the term "predetermined direction." As explained in Appellant's specification, proper barb orientation is important to "ensure[] that the barbs 'catch' and engage the adjacent tissue." ¶206. If the Anderson barbs pointed only in a proximal, distal, or inward direction, as suggested by the Examiner, they would not catch or engage adjacent tissue and they would not achieve the stated function. Thus, an "outward direction" is a necessary condition for the Anderson barbs to achieve their anchoring function. What Anderson does not

recognize or teach is that not all outward directions are sufficient to achieve this function. Appellant's claims recite orienting the barbs in a predetermined direction, whereas the orientation of Anderson's barbs is determined by the manner and extent of the expansion of the stent. Anderson teaches covering the entire circumference of the stent with barbs "so that exact placement of the anchors is less critical." See e.g. Anderson; col. 3, lines 5-8; col. 3, lines 33-39. Thus, Anderson expressly discloses barbs that point in a non-predetermined direction.

Appellant maintains that the Examiner has failed to establish that Anderson discloses a stent with each and every feature recited in the rejected claims and, therefore, has failed to establish a *prima facie* case of anticipation. Accordingly, the rejection of claims 45, 46, 48-50, 53, 58, and 60-62 is improper. Appellant respectfully requests that the Examiner's decision be REVERSED and these claims be allowed to pass to issuance.

Respectfully submitted,


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